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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,744	03/13/2006	Bandi Parthasaradhi Reddy	H1089/20032	9862
	7590 11/12/200 ISE, BERNSTEIN,	EXAMINER		
COHEN & POR	KOTILOW, LTD.	TRUONG, TAMTHOM NGO		
11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET			ART UNIT	PAPER NUMBER
PHILADELPH:	IA, PA 19103-2212		1624	
			NOTIFICATION DATE	DELIVERY MODE
			11/12/2008	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)	
	10/571,744	PARTHASARADHI REDDY ET AL.	
Office Action Summary	Examiner	Art Unit	
	TAMTHOM N. TRUONG	1624	
The MAILING DATE of this communication a Period for Reply	ppears on the cover sheet with the	correspondence address	
A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory perions after the reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the main earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATIO 1.136(a). In no event, however, may a reply be tiled will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE	N. mely filed  the mailing date of this communication. ED (35 U.S.C. § 133).	
Status			
Responsive to communication(s) filed on <u>3-1</u> This action is <b>FINAL</b> . 2b) ☑ The 3) ☐ Since this application is in condition for allow closed in accordance with the practice under	nis action is non-final. /ance except for formal matters, pr		
Disposition of Claims			
4) ☐ Claim(s) 1-61 is/are pending in the application 4a) Of the above claim(s) is/are withdred 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-61 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and Application Papers	rawn from consideration.		
9) The specification is objected to by the Examin 10) The drawing(s) filed on is/are: a) and a specificant may not request that any objection to the Replacement drawing sheet(s) including the correct of the oath or declaration is objected to by the left of the specific and the specific an	ccepted or b) objected to by the ne drawing(s) be held in abeyance. Se ection is required if the drawing(s) is ob	e 37 CFR 1.85(a). ojected to. See 37 CFR 1.121(d).	
Priority under 35 U.S.C. § 119			
12) ☐ Acknowledgment is made of a claim for foreignal All b) ☐ Some * c) ☐ None of:      1. ☐ Certified copies of the priority docume 2. ☐ Certified copies of the priority docume 3. ☐ Copies of the certified copies of the prapplication from the International Bure * See the attached detailed Office action for a list	nts have been received. Ints have been received in Applicat Iiority documents have been receiveau (PCT Rule 17.2(a)).	ion No ed in this National Stage	
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9/22/06.	4)  Interview Summary Paper No(s)/Mail D 5)  Notice of Informal I 6)  Other:	ate	

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#### **DETAILED ACTION**

Applicant's preliminary amendment of 3-13-06 has been entered. Claims 1-61 are pending.

### Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 1. Claims 16, 34-46 and 51-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:
  - a. Claim 16 recites the term "anti-solvent" which has indefinite metes and bounds because there is no definition for said term in the specification. It is unclear if this is another reagent, or a device, or a process.
  - b. Claim 34 and claims dependent thereon recite the limitation of "activated tetrahydro-2-furoic acid" which is not clear how it differs from the usual tetrahydro-2-furoic acid.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 1-8, 12-19, 21, 23, 34-36, 39, 41, 43, 45, 46 and 48-50 are rejected under 35 U.S.C. 102(b) as being anticipated by **Manoury** (4,315,007 cited on IDS). The alfuzosin base is described in Example II at the step of adding chloroform and sodium hydroxide, then dried over magnesium sulfate and evaporated under vaccumn (see column 3, lines 67-68 and column 4, lines 1-2).

The crystallization in alcoholic (e.g., isoamyl acohol) and/or ketonic solvent (e.g., acetone) can be found in Example I, column 3, lines 10-21, which states:

A suspension of 3.7 g (0.02 mol) of the above amine and 4.8 g (0.02 mol) of 4-amino-2-chloro-6,7-dimethoxyquinazoline in 35 ml of isoamyl alcohol is then heated to the reflux temperature. The mixture is kept at the boil for 7 hours and left to stand overnight and the precipitate is then filtered off and washed with ethyl acetate and then with ether.

The motor liquors from filtration are evaporated to dryness and the residue obtained is triturated with acetone. This yields a precipitate which is combined with the first and the whole is cyrstallised from a mixture of ethanol and ether. N<sub>1</sub>-(4-Amino-6,7-dimethoxyquinazol-2-yl)-N<sub>1</sub>-methyl-N<sub>2</sub>-(tetrahydrofuroyl-2)-propylenediamine hydrochloride, which melts at 235° C. (decomposition), is thus obtained.

The process recited in claims 34-36 can also be found in Example II in which the  $N_I$ -(4-amino-6,7-dimethoxyquinazol-2-yl)- $N_I$ -methylpropylenediamine reacts with tetrahydrofuroic

acid to yield alfuzosin base which gets converted to HCl salt in alcoholic solvent (i.e., 2-propanol).

The process recited in claims 23, 39, 41, 43, 45, 46, 48-50 -- converting the HCl salt of alfuzosin to alfusozin base-- can be found in Example II at the step of adding 2-N sodium hydroxide to the residue.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 9-11, 20, 22, 24-33, 37, 38, 40, 42, 44 and 51-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Manoury**. Said claims recite a process of crystallizing alfuzosin by using specific solvents such as: *methyl-isobutyl ketone, methanol, ethanol* which are not disclosed in Example I or II of Manoury. However, said solvents are within the same family as acetone, and isoamyl alcohol or 2-propanol.

Thus, at the time of the invention, it would have been obvious to develop the claimed process because it would have been within the level of the skilled chemist in this art to substitute

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one ketone or alcohol for another in the same family of alcohols for optimum yield. See the following MPEP excerpt:

Optimization Within Prior Art Conditions or Through Routine Experimentation Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also **Peterson**, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPO 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and **In re Geisler**, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAMTHOM N. TRUONG whose telephone number is (571)272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tamthom N. Truong/ Examiner, Art Unit 1624

/James O. Wilson/ Supervisory Patent Examiner, Art Unit 1624 Tamthom N. Truong Examiner Art Unit 1624 Page 6

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10-30-08